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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,605	02/21/2002	Thomas Keast	435712003521	7676

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 06/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/079,605	KEAST ET AL.
	Examiner	Art Unit
	Aaron Roane	3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *7-10,12,17 and 22-26* is/are withdrawn from consideration.

5)☒ Claim(s) *29* is/are allowed.

6)☒ Claim(s) *1,11,13-16,18-21,27,30 and 31* is/are rejected.

7)☒ Claim(s) *2-6 and 28* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 11, 13-15, 18-21, 27, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colley et al. (USPN 4,319,580) in view of Webster, Jr. (USPN 5,916,158).

Regarding claim 1, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a transducer assembly comprising a covering (76), at least one transducer (52) located towards the distal end of the elongate member and having at least a first (inner surface of annular ring 74) and second (outer surface of annular ring 74) pole, a first conductive medium (74) in contact with the first pole of the transducer and extending to at least a portion of an outer surface of the covering (76), at least two conducting members extending through at least a portion of the elongate member, at least a first conducting member (62A) coupled to the first conductive medium, a second conducting member (62B) extending through the proximal

end of the covering and electrically coupled to the second pole of the transducer, and a hollow conductive member (56) located at the distal end of the elongate member and electrically coupled to an electrical energy source, see col. 5-9 and figures 2, 4, 7 and 8. Colley et al. further disclose a tip (54B) having a round front (54B') and a back (small annular surface connecting portions 54A and 54C) surface, wherein the tip is located at the distal end of the elongate member, see beginning on col. 8, line 11 and ending on col. 9, line 30 and figures 7 and 8. Finally, Colley et al. disclose that the first and second conducting members are connected to a power supply having a "high frequency" power delivery (typically in the MHz range or the RF range), see beginning on col. 1, lines 55 and ending on col. 2, line 7. Colley et al. discloses that the hollow conductive member is an ECG electrode and not an ablation electrode. Webster, Jr. discloses a catheter device with electrodes and teaches the use of a catheter having electrodes capable of performing multiple functions such as ablation, pacing, electrograms, stimulation impedance measurements and mapping, see col. 2, lines 22-44. Webster, Jr. also discloses that the electrodes are coupled to an RF source in order to provide ablation energy, see col. 3, lines 10-18 and col. 9, lines 13-29. This provides the motivation for connecting the hollow conducting member of Colley et al. to an RF energy source in order to provide multiple functions to the electrode including ablation. Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Colley et al., as is well known in the art and demonstrated by Webster, Jr., to provide the hollow conducting member of Colley et al. with multiple functions in order to

perform these multiple functions wherein the electrodes are connected to an RF energy source.

Regarding claim 11, Colley et al. further disclose that the elongate member comprises an insulating material (58). Colley et al. disclose an embodiment having a flexible tubing (58 of figures 7 and 8) made of Tygon, a plastic which is electrically insulative, see col. 8, lines 48-54.

Regarding claim 13, Colley et al. further disclose an outer sheath (58) defining a lumen inside which the elongate member is located, see col. 8, lines 48-54 and figures 7 and 8.

Regarding claims 14 and 15, Colley et al. in view of Webster, Jr. discloses the claimed invention. Colley et al. disclose a third electrically conductive wire (60A) and the teaching of Webster et al. which provides the hollow electrically conductive tip electrode with multiple functions including ablation and discloses that the electrodes are coupled to an RF source in order to provide ablation energy.

Regarding claim 18, Colley et al. further disclose first and second conducting members that are electrically connected to a control unit to recognize and/or measure the Doppler shift between the transmitted and received signals. Colley et al. do not explicitly recite a control unit, but they do recite "a pulsed Doppler circuit (FIG. 9) energizes the transducer and provides a Doppler signal from return signals generated by the transducer as a result

of returns of transmitted ultrasonic energy. A circuit (FIGS. 10 and 11) processes the Doppler signal," see abstract. Also the circuitry and controls shown in figures 9-11 are inherently part of a control unit which is inherently coupled to the first and second conducting members disclosed by Colley et al. in order to provide the Doppler information.

Regarding claim 19, Colley et al. further disclose that the transducer is in the form of a piezoelectric transducer, abstract and col. 8, lines 32-39 and figures 7 and 8.

Regarding claims 20 and 21, Colley et al. further disclose that the covering comprises a first conductive tube (76), see col. 8, lines 32-39 and figures 7 and 8.

Regarding claim 27, Colley et al. further disclose that the hollow conductive member is fixed with respect to the transducer assembly, see figure 7.

Regarding claim 30, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a transducer means (74) located towards the distal end of the elongate member, a energy directing means (52) for directing the source signal and the reflected signal (see specifically the "omnidirectional" ability cited in col. 8, lines 31-62), a first conducting member (62A) coupled to the transducer means, a second conducting member (62B) coupled to the transducer means, wherein the first and second conducting members extend from the proximal portion of

the elongate member to the distal portion of the elongate member. Finally, an energy-conducting means located exterior to the transducer means and the directional means is inherently part of the Colley et al. disclosure, since the can not function without it, see col. 5-9 and figures 2, 4, 7 and 8.

Regarding claim 31, Colley et al. disclose an ultrasonic/electrical device and method of use, the device comprising an elongate member (54D), a ultrasonic transducer (52) located towards the distal end of the elongate member, an acoustically transmitting material (54) distal to the transducer, and a hollow conductive member (56) located at the distal end of the elongate member and circumferentially disposed about at least a portion of the elongate member, see col. 5-9 and figures 2, 4, 7 and 8.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Colley et al. (USPN 4,319,580) in view of Webster, Jr. (USPN 5,916,158) as applied to claim 1 above, and further in view of being well known in the art as shown by Gross (USPN 5,042,981) and Laufer et al. (USPN 6,135,997).

Regarding claim 16, Colley et al. in view of Webster, Jr. disclose the claimed invention except for explicitly disclosing that the hollow conducting member is made from a material from the group consisting of stainless steel, aluminum and titanium. It is very well known in the art to make components of surgical devices that come in contact with the skin from materials that are biocompatible, such as stainless steel as shown by Laufer

et al. (element 12) col. 10, lines 12-24 and col.13, lines 11-46 and aluminum which also nonallergenic by Gross (element 3) col. 5, lines 44-51. The rounded tip conductive member contacts the skin and therefore is would be made of stainless steel or aluminum. Therefore, at time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Colley et al. in view of Webster, Jr., as is well known in the art and shown by Laufer et al. and Gross, to make the rounded tip conductive member from stainless steel or aluminum in order to be compatible with the body.

Response to Arguments

Applicant's arguments filed on 3/5/2004 have been fully considered but they are not persuasive.

The arguments addressing the rejection to claim 1 based on Colley et al. in view of Webster, Jr., essentially pertain to the electrically conductive tip located at the distal end of the distal portion. The electrically conductive tip of Colley et al. was mistakenly reported as (78). The electrically conductive tip disclosed by Colley et al. is (56) not (78). The electrically conductive tip is a ring electrode and its location is at the distal end of the distal portion of the elongate member shown in the Colley et al. reference. The claim language does not recite that the entire distal tip is covered by an electrode having I) a cylindrical portion and dome portion or

II) a dome portion. The electrically conductive tip disclosed by Colley et al. meets the claim as set forth by the claim language.

The arguments addressing the rejection to claim 30 based on Colley et al. in view of Webster, Jr., pertain to the directional capabilities of the transducer assembly. The terms unidirectional and omnidirectional have been used to characterize the directional capabilities of the device. The actual propagation of ultrasonic waves/vibrations is in cylindrical wavefronts or wave patterns (see col. 5 and figure 2 of Colley et al.). This is essentially due the overall symmetry of the transducer which also happens to be cylindrical in nature. In other words, looking at the transducer, one can see quite easily that it has a cylindrical/ring design, and by no accident the wave pattern generated by the transducer has cylindrical symmetry, meaning that the waves are directed out, radially away from the transducer at the center of the wave pattern. This cylindrical wave pattern, although not directed in a single direction in a Cartesian coordinate system, is directed in a single, albeit in a cylindrical coordinate system, radially outward direction. Knowing the wave pattern of the transducer, it is plainly evident that the transducer disclosed by Colley et al. does possess directional means.

The arguments addressing the rejection to claim 31 based on Colley et al. in view of Webster, Jr., essentially pertain to I) the electrically conductive tip located at the distal end of the distal portion and II) an acoustically transmitting material distal to the transducer. First the electrically conductive tip of Colley et al. was mistakenly reported as (78). The electrically conductive tip disclosed by Colley et al. is (56) not (78). The electrically conductive tip is a ring

electrode and its location is at the distal end of the distal portion of the elongate member shown in the Colley et al. reference. The claim language does not recite that the entire distal tip is covered by an electrode having I) a cylindrical portion and dome portion or II) a dome portion. The electrically conductive tip disclosed by Colley et al. meets the claim as set forth by the claim language. Secondly, the recitation that an acoustically transmitting material distal to the transducer is an inherent aspect of the Cooley et al. disclosure. The electrically conductive tip has a back surface (small annular surface connecting portions 54A and 54C) that is mechanically coupled the transducer assembly (52) via member (54). As the transducer produces mechanical ultrasonic vibrations, these vibrations inherently travel through member (54), portions of member (54) are located distally to the transducer assembly and since the electrically conductive tip is mechanically coupled to member (54) the ultrasonic vibrations travel to and through member (54). The mechanical coupling of the transducer assembly and member (54) inherently provides that the portion of member (54) distal to the transducer transmits acoustical waves.

The arguments directed to the rejections of claims 1, 11, 13-15, 18-21 and 30 based on Ferek-Petric et al. (USPN 5,316,001) in view of Webster, Jr. (USPN 5,916,158) have been reviewed and considered. Since these rejections have been removed response to the arguments are rendered moot.

Due to the error regarding the hollow electrode (56) being initially reported as being element (78), ***this action is Non-Final.***

Allowable Subject Matter

Claim 29 is allowed.

Claims 2-6 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R.
June 3, 2004

MICHAEL PEFFLEY
PRIMARY EXAMINER